O.K. 4/30/99

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

M2584n

April 30, 1999

CERTIFIED - RETURN RECEIPT REQUESTED

Gourmet Foods International
3652 Trousdale Drive
Nashville, TN 37204

Attn: Michael Nguyen, President

WARNING LETTER - 99-NSV-12

Dear Mr. Nguyen:

An inspection of your sandwich manufacturing facilities by FDA Investigator David R. Heiar on March 23-24, 1999, found serious insanitary conditions and practices that could cause your finished products to be adulterated within the meaning of sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

The inspection found inadequate cleaning and sanitizing of processing equipment and food contact surfaces, unnecessarily prolonged holding of ingredients and prepared sandwiches at ambient room temperature, and the inadvisable cutting of whole turkey breasts without prior sanitizing or removal of the outer plastic wrappings. Quaternary ammonium solutions provided for employee hand sanitizing were overly-strong, possibly discouraging appropriate usage and/or resulting in unwanted residues. In addition, evidence of rodent activity was noted in the dry product and packaging storage areas of the plant.

We further note that the ingredients declaration on the labels for your 6 inch Turkey Sub sandwiches falsely declare American cheese, a standardized food [See 21 CFR 133.169(e)(2)(ii), copy enclosed], as an ingredient; the labels should declare the actual cheese product being used - "Pasteurized Process American Cheese Substitute," or you should switch to the declared cheese ingredient. Otherwise, the product is misbranded within the meaning of sections 403(a)(1) and 403(g) of the Act.

The above noted observations are not intended as an all-inclusive list of existing deficiencies at your facility. It remains your responsibility to assure compliance with all requirements of the Act.

You should take prompt action to correct these noted violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days after receipt of this letter of the specific steps you have taken to correct the noted violations and prevent the recurrence of any similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the correction will be made.

Your reply should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

M. Anthony Abel, I for

Howard E. Lewis
Acting Director
Nashville District

HEL/kl